

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.: 09/997,450
Applicant: Shamim M. Malik et al.
Filed: November 30, 2001
Art Unit: 3731
Examiner: Ryan J. Severson
Docket No.: 050623.00061
Confirmation No.: 3442
Customer No.: 45159
Title: A Modified Surface For An Implantable Device And A Method Of
Producing The Same

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF

Dear Sir:

This Appeal Brief is submitted pursuant to the Notice of Appeal that was filed on 10 August 2009 in response to the Final Rejection mailed on 12 May 2009 in which the Examiner reiterated his rejection of 9 July 2008 in which all pending claims were rejected.

I. REAL PARTY IN INTEREST

The real party in interest with regard to this appeal is Abbott Cardiovascular Systems Inc., with its primary place of business at 3200 Lakeside Drive, Santa Clara, California 95054. The present application was filed on November 30, 2001. The assignment of application serial no. 09/997,450 to Advanced Cardiovascular Systems, Inc., was recorded in the United States Patent and Trademark Office on November 30, 2001, in Reel 012339, Frame 0797. Abbott Cardiovascular Systems Inc. purchased the vascular device division and all relevant intellectual property including the instant application of Advanced Cardiovascular Systems, Inc. (Guidant Corporation) in April 2006.

II. RELATED APPEALS AND INTERFERENCES

Appellant, Appellant's assignee, and their counsel are not aware of any related appeals or interferences which would affect, be affected by, or have a bearing on the instant appeal.

III. STATUS OF CLAIMS

Claims 11, 12, 15, 16, 20, 22, 23, 28 – 33, and 35 – 41 have been canceled without prejudice to reclaiming the subject matter therein in a subsequent application.

Claims 1, 7 – 10, 13, 14, 17, 18, 26, 27, 34, and 42 – 45 have been withdrawn by the examiner as being drawn to a non-elected species.

Claims 2 – 6, 19, 21, 24, and 25 have been finally rejected and are the subjects of this appeal.

IV. STATUS OF AMENDMENTS

There are no unentered amendments.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The appealed application contains two independent claims, claims 19 and 21. The support for claim 19 can be found in the specification as follows: Independent claim 19¹ is directed to a method modifying a stent surface (specification paragraphs [0007], [0008], [0015], and [0019]). The method includes implanting Ti or N into the surface of the stent on a molecular or atomic level (specification paragraphs [0008], [0016], [0018], [0021], and Figure 2C2), then implanting TiN over the Ti or N (specification paragraph [0021], and Figure 2C2), and followed by forming a layer of a TiN_xO_y compound over at least some of the areas where TiN has been implanted (specification paragraphs [0008] and [0021], and Figure 2C2).

¹ 19. A method of modifying a stent surface, comprising implanting Ti or N into the surface of the stent on a molecular or atomic level, followed by implanting TiN over the Ti or N, and followed by forming a layer of a TiN_xO_y compound over at least some of the areas where TiN has been implanted.

The support for claim 21 can be found in the specification as follows: Independent claim 21² is directed to a stent. The stent includes a first region (reference numeral 20 in Figure 2C2) having Ti or N implanted on a molecular or atomic level at a depth within at least a region of a surface of the stent (specification paragraph [0021] and Figure 2C2). The stent includes a second region (reference numeral 24 in Figure 2C2) that is over the first region having TiN implanted on a molecular or atomic level at a depth within at least a region of a surface of the stent (specification paragraph [0021] and Figure 2C2). The stent further includes a layer of TiN_xO_y compound (reference numeral 22 in Figure 2C2) over the second region (specification paragraph [0021] and Figure 2C2).

Dependent claims 2 – 6, 24, and 25 depend, either directly or indirectly, from claim 21.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The ground for rejection to be reviewed in this appeal is:

Whether claims 2 – 6, 19, 21, 24, and 25 are rendered obvious, and are therefore unpatentable under 35 U.S.C. §103(a), over Lazarov et al., United States Patent No. 6,110,204 (Evidence Appendix, Exhibit A) (Lazarov), in view of Malik et al., *J. Vac. Sci. Technol. A*, **15**(6), Nov/Dec 1997 (Evidence Appendix, Exhibit B) (Malik).

² 21. A stent comprising: a first region having Ti or N implanted on a molecular or atomic level at a depth within at least a region of a surface of the stent; a second region over the first region having TiN implanted on a molecular or atomic level at a depth within at least a region of a surface of the stent; and a layer of TiN_xO_y compound over the second region.

VII. ARGUMENTS

Claims 2 – 6, 19, 21, 24, and 25 are patentable under 35 U.S.C. § 103(a) over Lazarov in view of Malik.

The Examiner's Contentions:

In the Final Office Action of 12 May 2009 (Evidence Appendix, Exhibit C) (Final Office Action), the Examiner maintained his rejection of claims 2 – 6, 19, 21, 24, and 25 over Lazarov in view of Malik that was made in the Office Action of 9 July 2008 (Evidence Appendix, Exhibit D) (July 2008 Office Action). According to the Examiner, Lazarov teaches “the titanium-nitride-oxide (TiN_xO_y) compound disposed about a stent substrate substantially as claimed.” However, the Examiner admits that Lazarov does not disclose “the compound is implanted on a molecular level within the surface of the stent.” Then the Examiner cited Malik for this deficiency stating that Malik “teach[es] implantation of various compounds (including Ti, N, and O) within the surface of a metallic substrate to increase the ability of the compound to adhere to the substrate.” Finally, the Examiner concludes that Appellants’ claims are obvious because “one of ordinary skill in the art . . . [would] have implanted the compound of Lazarov within the surface of the stent, as taught by Malik et al., to increase the adhesion between the compound and the substrate (the stent).”

Appellant's Response:

Appellant traverses the Examiner's rejection for the following reasons:

Implantation of TiN is not disclosed

Appellants reiterate their position taken in the Response of 24 February 2009 (Evidence Appendix, Exhibit E) (Response) in reply to the Notice of Non-Compliant Response, which is a response to the Office Action of 9 July 2008. The Examiner is incorrect, Malik does not “teach implantation of various metallic compounds (including Ti, N, and O). . . .” With respect to implantation, Malik states “[a]fter sputter cleaning, the substrate may be implanted with a relevant ion species for improved adhesion” (page 2876, column 1, lines 10 – 12) and “[t]he PSII [plasma source ion implantation] technique has been used to implant nitrogen, oxygen, carbon and boron ions into various materials” (page 2875, column 1, lines 11 – 13). The only specific experimental example of implantation provided in Malik is “a methane plasma was used to implant the carbon ions” (page 2877, column 1, lines 9 – 11). In sum, Malik teaches the general concept of ion implantation. However, with respect to the meaning of the term “relevant ions” used to improve adhesion of a subsequent layer, the only specific teaching of Malik is the implantation of carbon ions in the context of the formation of a diamond-like carbon layer on a substrate.

In contrast to the Examiner’s assertions, Malik does not teach the implantation of Ti. Malik does not teach the implantation of TiN or other Ti alloys. Malik does teach “TiN_x films were formed on the inner surface of the cylinder (substrate)” (page 2877, column 2, lines 9 and 10). Malik also teaches the use of Ti as a sputtering target, and “the material sputtered from the cathode (target) deposits on the substrate . . .” (page 2875, column 1, lines 3 – 5).

In reply to Appellants’ arguments summarized above, the Examiner has stated, in his Response to Arguments (item 4 of the Final Office Action), “Malik was not relied upon for teaching implantation of the entire alloy. Malik was used to show that ion implantation with materials similar or the same as those in the alloy can be implanted at a depth within the surface

of a stent.” As noted above, Malik discloses the implantation of oxygen, nitrogen, carbon, and boron, but does not disclose implantation of Ti, TiN or any other alloy of Ti. There is nothing in the implantation of oxygen, nitrogen, carbon, and boron that teaches or suggests the implantation of TiN.

The Examiner has improperly interpreted Appellants’ Claims

In his Response to Arguments (item 4 of the Final Office Action), the Examiner has also stated that “the claims only require that the Ti or N to be implanted within the surface of the stent.”

Appellants point out that claim 21 recites a stent having “a first region having Ti or N implanted on a molecular or atomic level at a depth within at least a region of a surface of the stent; a second region over the first region having TiN implanted on a molecular or atomic level at a depth within at least a region of a surface of the stent,” and “a layer of TiN_xO_y compound over the second region.” Thus, in the first region only Ti or N is implanted, but there is also a second region that has TiN implanted.

Similarly, claim 19 recites “a method of modifying a stent surface.” The method comprises the operations of “implanting Ti or N into the surface of the stent on a molecular or atomic level,” that is “followed by implanting TiN over the Ti or N,” and “followed by forming a layer of a TiN_xO_y compound over at least some of the areas where TiN has been implanted.” Thus, claim 19 also includes implantation of TiN.

As a result, the Examiner is incorrect when he states “the claims only require that the Ti or N to be implanted within the surface of the stent.”

The Examiner has improperly interpreted Malik

In his Response to Arguments (item 4 of the Final Office Action), the Examiner further elaborates “Malik clearly teaches implantation of nitrogen (N) compounded with Titanium (Ti) in the surface, as claimed.”

As noted above Malik only discloses the implantation of oxygen, nitrogen, carbon, and boron. Malik does not disclose the implantation of Ti, TiN or any other alloy of Ti. Malik repeatedly refers to a film of TiN_x on a surface (page 2875, column 1, line 25; page 2876, column 2, lines 24 – 26; page 2877, column 1, lines 31 – 33; page 2877, column 2, lines 9 – 11; page 2878, column 1, lines 4 – 6 and lines 24 – 26; and page 2878, column 2, line 20 – page 2879, column 1, line 1). In summary, Malik does not disclose implantation of TiN, but the formation of a TiN film on a surface.

The Tri-Region Construct is not Taught

Appellants again reiterate the position taken in the Response. Lazarov and Malik, alone or in combination, fail to teach the tri-region construct as claimed in claims 19 and 21. More specifically, the references fail to teach a “first region having Ti or N implanted on a molecular or atomic level at a depth within at least a region of a surface of the stent; a second region over the first region having TiN implanted on a molecular or atomic level at a depth within at least a region of a surface of the stent; and a layer of TiN_xO_y compound over the second region,” as recited by claim 21 and “implanting Ti or N into the surface of the stent on a molecular or atomic level, followed by implanting TiN over the Ti or N, and followed by forming a layer of a TiN_xO_y compound over at least some of the areas where TiN has been implanted,” as recited by claim 19.

The Examiner has admitted “Lazarov reference does not disclose the compound [titanium-nitride-oxide (TiN_xO_y)] is implanted on a molecular level within the surface of the

stent.” As noted above, Malik teaches the implantation of carbon, nitrogen, oxygen, and boron ions, and other unspecified “relevant ions.” Thus, although Malik does disclose that a compound may be “implanted on a molecular or atomic level at a depth within at least a region of a surface of the substrate [stent],” Malik does not disclose “a second region over the first region having” another compound “implanted on a molecular or atomic level at a depth within at least a region of a surface of the stent.” The tri-region construct is neither disclosed, nor rendered obvious by, Lazarov or Malik, alone or in combination.

In his Response to Arguments (item 4, Final Office Action), the Examiner has stated that “Lazarov teaches layering [of] TiN_xO_y .” Appellants fail to see the relevance of layering of TiN_xO_y on the surface of a device to Appellants’ claims. As noted above, claim 21 is directed to a stent with a “first region having Ti or N implanted . . . ; a second region over the first region having TiN implanted . . . ; and a layer of TiN_xO_y compound over the second region.” Regarding claim 19, it is a method directed to “implanting Ti or N into the surface of the stent on a molecular or atomic level, followed by implanting TiN over the Ti or N, and followed by forming a layer of a TiN_xO_y compound over at least some of the areas where TiN has been implanted.” Thus, neither independent claims 19 nor 21 recite multiple layers on the surface of the device. As a result the fact that “Lazarov teaches layering [of] TiN_xO_y ” is irrelevant.

The Examiner has not established a *Prima Facie* case of Obviousness

As Appellants discussed above, Lazarov and Malik, either alone or in combination, fail to teach, suggest, or render obvious, TiN implanted on a molecular or atomic level at a depth within at least a region of a surface of the stent, and the tri-region construct of Appellants’ claims 19 and 21. Both of these arguments were previously presented in the Response.

In his Response to Arguments (item 4 in the Final Office Action), the Examiner has stated that “Malik was not relied upon for teaching implantation of the entire alloy. Malik was used to show that ion implantation with materials similar or the same as those in the alloy can be implanted at a depth within the surface of a stent.” According to the Examiner, “Lazarov teaches layering [of] TiN_xO_y .” It is the Examiner’s position that “the total[ity] of evidence shows that it is known in the art to implant TiN in the surface of a stent, and to have a covering of TiN_xO_y over the surface of the stent.” The Examiner concludes that “one of ordinary skill in the art at the time the invention was made would have found it obvious to combine the teachings of Lazarov and Malik to reach the claimed invention.”

The Examiner has not established a *prima facie* case of obviousness. As best understood by Appellants, the Examiner is essentially stating that the missing elements mentioned above are “obvious,” thus rendering Appellants’ claims obvious. However, as recently noted by the Board of Patent Appeals and Interferences (BAPI) in a similar case in which the Examiner had asserted that the missing elements were “obvious” in light of the references, “‘obviousness requires a suggestion of all limitations of a claim.’ *CFMT, Inc. v. Yieldup Interm. Corp.*, 349 F.3d 1333, 1342 (Fed Cir. 2003) (citing *In re Royka*, 490 F.2d 981, 985 (CCPA, 1974))” (BAPI, Appeal 2007-3733). Further, “rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR International Co. v. Teleflex Inc. et al.*, 127 S. Ct. 1727, 1741 (2007).

First, as discussed above, the totality of evidence does not show that it was known to implant TiN in the surface of a stent. Malik only discloses the formation of a TiN_x film on the surface of a stent, but not the implantation of TiN. As admitted by the Examiner, Lazarov does not disclose implantation.

Second, Malik does not disclose the implantation of compounds with the exception of implantation of oxygen, nitrogen, carbon, and boron. Oxygen, nitrogen, carbon, and boron are different from a heavy metal such as Ti, and even more different from an alloy of Ti, such as TiN. There is nothing in the disclosure of the implantation of oxygen, nitrogen, carbon, and boron that would teach, suggest, motivate, hint, or render obvious the implantation of TiN. Moreover, the formation of a TiN_x film on the surface of a substrate would not have led one to implant TiN in a substrate.

Third, multiple layers of TiN_xO_y on the surface does not render obvious the tri-region construct of claims 19 and 21. The disclosure of multiple surface layers is not relevant to either claims 19 or 21 which recite one layer on the surface.

It is clear that the Examiner is relying upon the hindsight of Appellants' specification and using it as a template to reach the conclusion that the claims are obvious in light of the references. The Examiner has not explained how the combination of the two references would have led one of ordinary skill in the art to the device of claim 21 with the two regions and a layer on top of the second region, or the method of claim 19 which involves the three processing operations. Additionally, the Examiner has not explained how the combination of the references would have led one of skill in the art to the implantation of TiN.

CONCLUSION

The Examiner has failed, as a matter of law, to set forth a case of unpatentability of claims 2 – 6, 19, 21, 24, and 25. Appellant therefore respectfully requests that the Board reverse the Examiner's rejection and order that the application proceed to issue.

The Commissioner is hereby authorized to charge the **Squire, Sanders, and Dempsey Deposit Account No. 07-1850** for any fees due.

Date: October 12, 2009

Squire, Sanders & Dempsey L.L.P.
One Maritime Plaza, Suite 300
San Francisco, CA 94111
Telephone (415) 954-0200
Facsimile (415) 393-9887

Respectfully submitted,

/Gloria M. Gusler, Reg. No. 50,282/
Gloria M. Gusler, Ph.D.
Attorney for Appellant
Reg. No. 50,282

VIII. Claims Appendix

Listing of Claims:

1. (Withdrawn) A stent comprising a compound including Ti, N, C, implanted on a molecular or atomic level at a depth within at least a region of a surface of the stent and a layer of TiN_xC_y disposed over the compound.
2. The stent of Claim 21, wherein x is 1 and y is 1 or 2.
3. The stent of Claim 21, wherein the depth of an implanted TiN_xO_y compound is not greater than about 2000 Å from the surface of the stent.
4. The stent of Claim 21, wherein the layer of TiN_xO_y is exposed on the surface of the stent.
5. The stent of Claim 4, wherein x is 1 and y is 1 or 2.
6. The stent of Claim 4, wherein the layer of TiN_xO_y compound is not more than about 48,000 Å in thickness.
7. (Withdrawn) The stent of Claim 1, wherein the stent is made from stainless steel.
8. (Withdrawn) The stent of Claim 1, wherein the surface is the tissue-contacting surface of the stent.
9. (Withdrawn) A stent comprising a layer of TiN_xC_y on a surface of the stent and a subsurface compound including Ti, N, or TiN disposed beneath the layer of TiN_xC_y , wherein the subsurface compound is intermixed with a surface material of the stent.
10. (Withdrawn) The stent of Claim 9, wherein a region of the layer of TiN_xC_y is implanted at a depth within a surface of the stent.

11. – 12. (Canceled)
13. (Withdrawn) A method of modifying a surface of a stent, comprising implanting a compound including Ti, N, C on a molecular or atomic level at a depth within a surface of the stent, followed by depositing TiN_xC_y over the implanted compound.
14. (Withdrawn) The method of Claim 13, wherein x is 1 and y is 1 or 2.
15. – 16. (Canceled)
17. (Withdrawn) The method of Claim 13, wherein the stent is made from stainless steel.
18. (Withdrawn) The method of Claim 13, wherein prior to the act of implanting the compound including Ti, N, C within the surface of the stent, the method comprises implanting Ti, N or TiN within the surface of the stent.
19. A method of modifying a stent surface, comprising implanting Ti or N into the surface of the stent on a molecular or atomic level, followed by implanting TiN over the Ti or N, and followed by forming a layer of a TiN_xO_y compound over at least some of the areas where TiN has been implanted.
20. (Canceled)
21. A stent comprising: a first region having Ti or N implanted on a molecular or atomic level at a depth within at least a region of a surface of the stent; a second region over the first region having TiN implanted on a molecular or atomic level at a depth within at least a region of a surface of the stent; and a layer of TiN_xO_y compound over the second region.
22. – 23. (Canceled)

24. The stent of Claim 21, wherein the stent is made from stainless steel.
25. The stent of Claim 21, wherein the surface is the tissue-contacting surface of the stent.
26. (Withdrawn) A stent comprising a layer of TiN_xC_y exposed on the surface of the stent, the stent having a surface material different than TiN_xC_y and a compound including Ti, N, or TiN, disposed beneath the layer of TiN_xC_y such that the compound is blended with the surface material of the stent.
27. (Withdrawn) The stent of Claim 26, wherein a region of the layer of TiN_xC_y is implanted at a depth within a surface of the stent.
28. – 33. (Canceled)
34. (Withdrawn) A stent comprising a TiN_xC_y compound implanted on a molecular or atomic level at a depth within at least a region of a surface of the stent.
35. – 41. (Canceled)
42. (Withdrawn) The stent of Claim 34, additionally comprising a layer of a TiN_xC_y compound on the region of the surface of the stent wherein the TiN_xC_y compound is implanted.
43. (Withdrawn) A method of modifying a stent surface, comprising implanting on a molecular or atomic level Ti, N, or TiN into the surface of the stent and forming a layer of a TiN_xC_y compound over the areas where Ti, N, or TiN has been implanted.

44. (Withdrawn) A method of modifying a surface of a stent, comprising implanting a TiN_xC_y compound on a molecular or atomic level at a depth within a surface of the stent or depositing the compound on the surface of the stent.
45. (Withdrawn) The stent of Claim 1, wherein the layer of TiN_xC_y is exposed on a surface of the stent.

IX. Evidence Appendix

Attached hereto are the following Exhibits:

- A. U.S. Pat. No. 6,110,204 to Lazarov et al.
- B. Malik et al., *J. Vac. Sci. Technol. A*, **15**(6), Nov/Dec 1997
- C. Final Office Action mailed on 12 May 2009
- D. Office Action mailed on 9 July 2008
- E. Response of 22 February 2009 to Notice of Informal or Non-Responsive
Amendment of 27 January 2009

EVIDENCE APPENDIX A



US006110204A

United States Patent [19]

Lazarov et al.

[11] **Patent Number:** **6,110,204**
 [45] **Date of Patent:** **Aug. 29, 2000**

[54] **IMPLANT**[75] Inventors: **Miladin Lazarov; Isabella Mayer,**
both of Munich, Germany[73] Assignee: **Huber & Schussler,** Munich, Germany[21] Appl. No.: **08/913,268**[22] PCT Filed: **Feb. 22, 1996**[86] PCT No.: **PCT/DE96/00322**§ 371 Date: **Feb. 9, 1998**§ 102(e) Date: **Feb. 9, 1998**[87] PCT Pub. No.: **WO96/25960**PCT Pub. Date: **Aug. 29, 1996**[30] **Foreign Application Priority Data**

Feb. 22, 1995 [DE] Germany 195 06 188

[51] **Int. Cl.⁷** **A61F 2/00**; A61L 27/04;
A61L 27/28; A61L 33/00[52] **U.S. Cl.** **623/11.11**; 623/1.46; 623/23.6;
427/2.24; 427/453; 427/126.3; 606/76;
428/304.4; 428/315.5[58] **Field of Search** 623/11, 16, 18,
623/12; 606/76; 604/265; 427/2.24, 453,
126.3; 428/304.4, 315.5[56] **References Cited****U.S. PATENT DOCUMENTS**

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0 410 711 A1 1/1991 European Pat. Off. .
WO 95/17533 6/1995 WIPO .**OTHER PUBLICATIONS**Dion, et al., "Haemocompatibility of Ti6A14V Alloy," *Bio-materials*—14(2):122–126 (1993).Bolz, et al., "Haemocompatibility Optimisation of Implants by Hybrid Structuring," *Med. & Biol. Eng. & Comput.*,—31:S123–S130 (1993).Brady, Robert F., Jr., "Coming to an Unsticky End," *Nature*—368(3):16–17 (1994).

Kondo, et al., "Manufacture of Prosthetic Implants from Titanium and Its Alloy," Abstract (1992).

Kondo, et al., "Ceramic-coated Prosthetic Implants," Abstract (1989).

Primary Examiner—Mickey Yu*Assistant Examiner*—Choon P. Koh*Attorney, Agent, or Firm*—Albert P. Halluin; J. David Smith; Howrey Simon Arnold & White, LLP[57] **ABSTRACT**

The present invention relates to an implant for use in the human body, an implant substrate being coated with a material which contains chemical compounds between one or more metals (M) of group IV A of the periodic system, nitrogen (N) and oxygen (O), 2 to 45% of the volume in the coating material being formed by voids whose sizes range from (0.4 nm)³ to (50 nm)³, and the remaining volume having a composition of a metal of group IV A of the periodic system to nitrogen to oxygen of 1:(0.1 to 1.7):(0.1 to 1.7), a material having formula MN_xO_y (wherein x,y= 0.1–1.7) resulting.

The invention also relates to the use of this implant for implantation into the animal or human body.

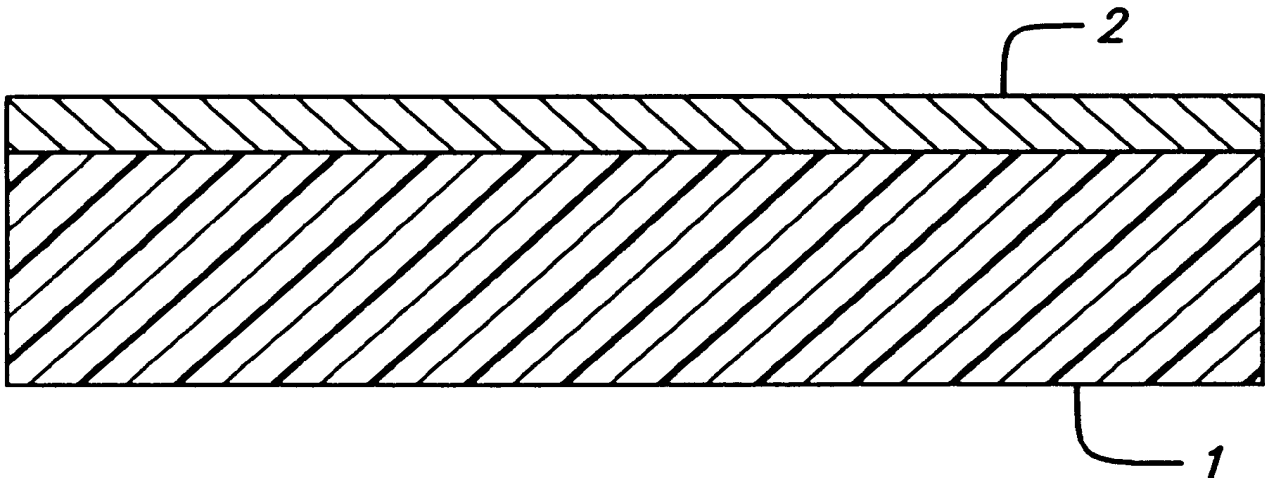
16 Claims, 2 Drawing Sheets

FIG. 1

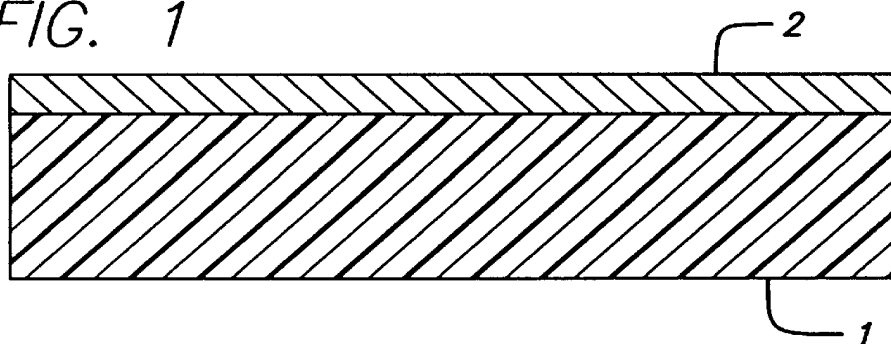


FIG. 2

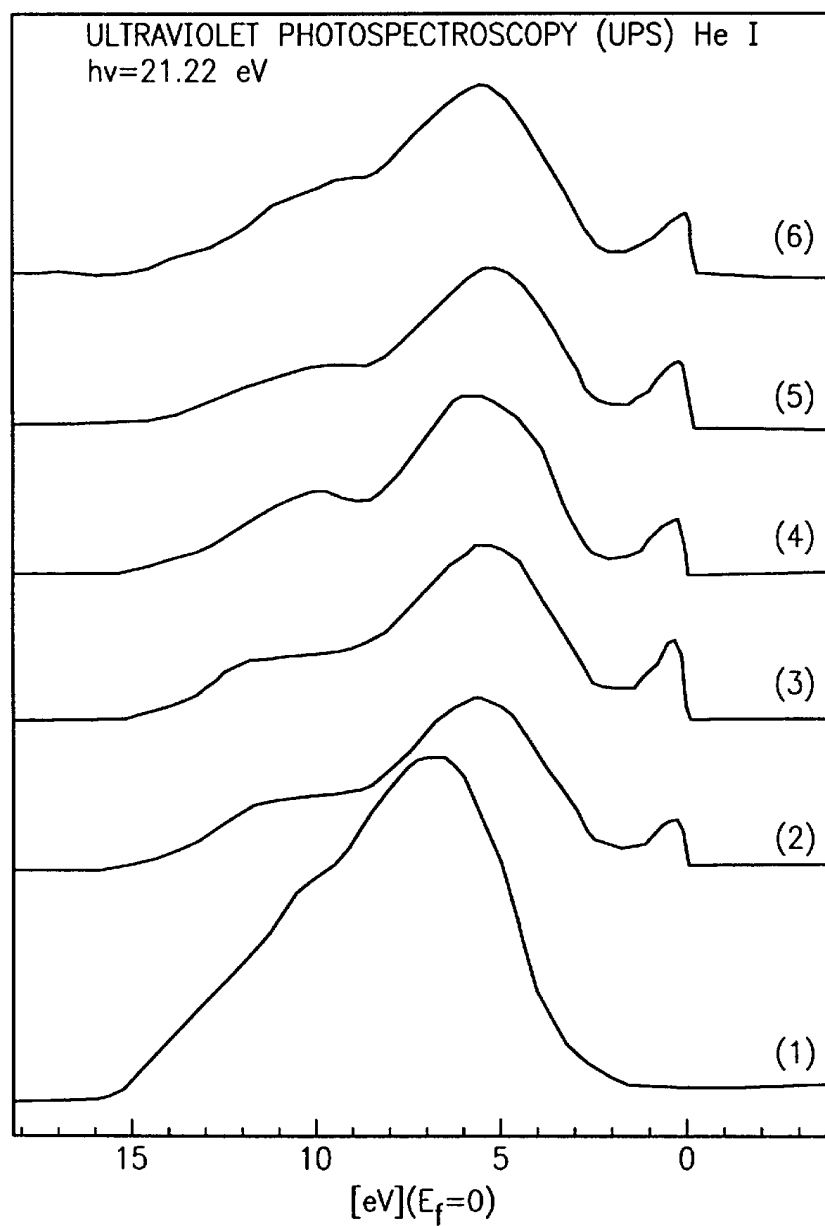
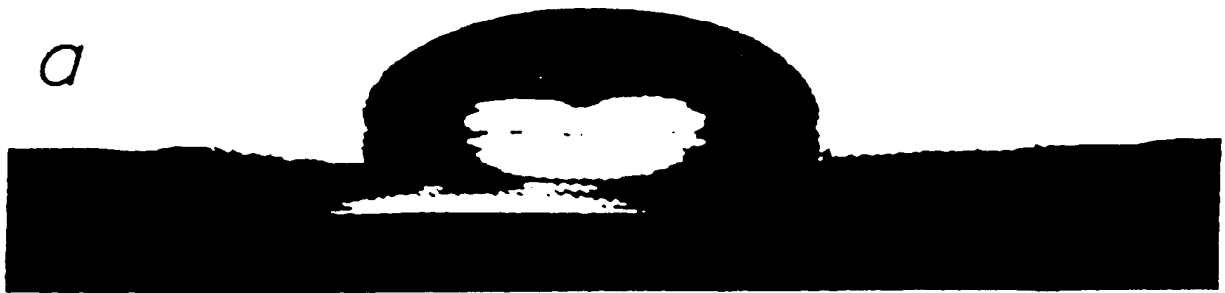


FIG. 3



1 IMPLANT

The present application is a U.S. nationalization pursuant to 35 U.S.C. 371 of PCT/DE96/00322 filed on Feb. 22, 1996 which is in turn based on German Patent Application No. 195 06 188.8 filed on Feb. 22, 1995.

This invention relates to implants.

Various artificial materials are introduced into the human body as a short-term or relatively long-term implant for diagnosis and treatment (catheters, probes, sensors, stents, artificial heart valves, endotracheal tubes etc.). The selection of the material for these implants depends on the stability and geometry required to insure a certain function of the implant. In order to meet these functional demands, it is often not possible to pay sufficient regard to the fact of whether these materials are biocompatible. Therefore, it is useful to improve the materials from which these implants are made by coatings which are compatible with blood and tissue. Coatings are required which activate the coagulation system only to a minor degree, and which cause few endogenous defense reactions thus reducing the deposit of thrombi and biofilm on the implant surface. A coating is useful for all materials which are directly introduced into the bloodstream, e.g. for vascular prostheses, stents, artificial heart valves, as well as for implants which are in contact with tissue, e.g. cardiac pacemakers or defibrillators and for implants which are in contact with body fluids, e.g. bile duct drains, catheters for draining urea and cerebrospinal fluid, and endotracheal resuscitation tubes. The blood compatibility of implants is influenced decisively by their surface properties. In order to avoid the formation of thrombi ("antithrombogenicity"), relative smoothness is necessary to prevent the deposit and destruction, of corpuscular components of the blood and activation of the coagulation system. In addition, direct charge exchange processes must be prevented between coagulation-specific proteins and the implant surface.

It is known to use coatings made of pyrolytic carbon as a common material for heart valves to meet these demands. In addition, it is known to use semi-conducting materials, e.g. a-SiC:H as an implant coating, to prevent the charge exchange processes between the coagulation-specific proteins and the implant surface (A. Bolz, M. Schaldach, "Haemocompatibility optimisation of implants by hybrid structuring", *Med. & Biol. & Comput.*, 1993, 31, pp. 123-130). Furthermore, it is known to employ $\text{Ti}_6\text{Al}_4\text{V}$ as a coating (I. Dion, C. Baquey, J.-R. Monties, P. Havlik, "Haemocompatibility of $\text{Ti}_6\text{Al}_4\text{V}$ alloy", *Biomaterials*, Vol. 4, 1993, pp. 122-126). A plurality of plastics have also been investigated in the field of polymer chemistry to produce non-adhering surfaces. In this field as well, the problem has not yet been solved satisfactorily (R. F. Brady Jr., "Coming to an unsticky end", *Nature*, Vol. 368, 1994, pp. 16-17).

Although implants having a carbon coating and a porous structure meet the demands made on the surface properties, they have the drawback that an electron transfer caused by tunneling of occupied, valence band-like states of the protein to free states of the solid leads to cleavage of fibrinogen in the blood. The resulting fibrin monomers polymerize and produce an irreversible thrombus. Although implants made of rutile ceramics prevent these charge exchange processes, they were not ready for series production because of the high production costs. Although implants having a coating made of amorphous carbon (a-SiC:H) can be produced in a cost-effective fashion, the drawback of this material consists in that it is not hard enough for certain applications. This material is presently produced by means of CVD methods

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which require great heating of the substrate as an additional problem, so that application is made more difficult for a large number of heat-sensitive basic materials. In addition, this material has a fixed band gap and low conductivity. Both properties lead to the formation of thrombi rather than preventing them.

Therefore, it is the object of the present invention to provide an implant of the above-mentioned kind with a surface by which the activation of blood coagulation accompanied by the formation of thrombi as well as the formation of a biofilm are reduced significantly.

The object is achieved by an implant according to the present invention.

An implant within the meaning of this invention shall comprise every device or every means which can be implanted into an animal or human body or inserted therein on a relatively long-term basis and short-term basis, respectively, or be attached to the animal or human body. The following examples are mentioned: catheters, probes, sensors, stents, artificial heart valves, endotracheal tubes, cardiac pacemakers.

The material for coating the implant, i.e. the coating material, contains the following chemical compounds: one or more metals of the IVA group of the periodic table, nitrogen and oxygen. 2-45%, preferably 10-43%, more preferably 20-35%, of the volume is formed by voids whose sizes range from $(0.4 \text{ nm})^3$ [$\approx 0.064 \text{ nm}^3$] to $(50 \text{ nm})^3$ [$\approx 125000 \text{ nm}^3$], preferably $(0.4 \text{ nm})^3$ to $(20 \text{ nm})^3$. The gaps frequently described in the literature (e.g. John A. Thornton, *The microstructure of sputter-deposited coatings*, *J. Vac. Sci. Technol. A4* (6), 1986, pp. 3059-3065) and formed by columnar film growth are not meant to be within the scope of these voids. Thus, it is not the known gaps between the columns that are of concern but rather voids within these columns. These very voids result in the properties specific to the invention. The remaining volume of the coating material (98-55%, preferably 90-57%, especially preferably 80-65%) has a composition of a metal of group IVA of the periodic table to nitrogen to oxygen such as 1:(0.1 to 1.7):(0.1 to 1.7), preferably 1:(0.4 to 1.2):(0.1 to 1.2). The formula of the material is MN_xO_y , "M" being a metal of group IVA of the periodic table and x and y, respectively, being values from 0.1 to 1.7. The above ratios refer to the particle number and molar ratios, respectively. The metal of group IVA of the periodic table may be titanium, zirconium or hafnium or a mixture of two or the three metals. Preferably, it is titanium.

As far as the sizes of the voids are concerned, it is preferred that they occur in the lower range, i.e. that they are preferably not greater than $(15 \text{ nm})^3$. The "remaining volume" of the material preferably comprises one or more chemical compounds selected from the group consisting of MN_x ($x=0.7$ to 1.2), MO_x ($x=0.7$ to 1.2), Magnelli phases of the M—O system (MnO_{2n-1}), MO_2 , M_2N (wherein M=metal of group IVA of the periodic system) as well as about 0-30%, preferably 0.5-5%, of carbon compounds of a metal of group IVA of the periodic table. By the addition of these carbon compounds the spectrum of possible uses of the coating is extended and the stability is increased, which has been shown e.g. in the case of urine catheters. Minor amounts of titanium carbides as impurities are usually not disturbing, they even permit a cheaper production of the coating. The possibility that the chemical phases may preferably be present in the coating material in crystalline or amorphous form, prevents the apposition and destruction of corpuscular components of the blood, so that the involved activation of the coagulation system is prevented. Therefore,

the coating material counteracts the formation of thrombi, i.e. shows "antithrombogenic" properties.

The possibility of introducing a fractal size distribution of the voids, permits an essential extension of the surface as used e.g. for pacemaker electrodes. A greater surface permits a reduction of the electrical impedance and thus a longer service life of a pacemaker battery.

Furthermore, the coating material preferably includes that the real part of the refractive index for the X-ray wavelength of 0.0709 nm ranges from 0.9999984 to 0.9999973. The mass density of the coating material preferably ranges from 3.5 to 5.4 g/cm³, preferably from 3.7 to 4.5 g/cm³, more preferably from 3.8 to 4.2 g/cm³.

In addition to the metals of group IVA of the periodic table, the coating material may also contain niobium, tantalum, tungsten, molybdenum or alloys thereof as additional metals, which improves the corrosion resistance of the coating.

When the material contains hydrogen (dissolved or preferably in bound form), free bonds are saturated in the amorphous phases. This affects the electron state distribution which is more favorable for biocompatibility.

The thickness of the coating ranges preferably from 3 nm to 3 mm, more preferably from 10 nm to 2 mm, most preferably from 30 to 71 nm.

The coating preferably has a specific resistance ranging from 30 to 30000 μΩ.cm, preferably 100 to 6000 μΩ.cm, more preferably 2000 to 3000 μΩ.cm. The specific resistance can be adjusted without any problem by the selection of the void fraction or portion. The specific resistance of the material increases when voids are added. For example, the specific resistance of TiN_{0.98}O_{0.2} may be 70 μΩ.cm when the void portion is 3% and increases up to about 650 μΩ.cm when the void portion is 40%.

The coating is disposed as a thin layer on a substrate suitable as an implant. This substrate may be made of plastics, e.g. polyester, polyamide, polyurethane (PUR), polyethylene (PE), polytetrafluoroethylene (PTFE) or DACRON[®] or of a metal such as molybdenum, silver, gold, copper, aluminum, tungsten, nickel, chromium, zirconium, titanium, hafnium, tantalum, niobium, vanadium, iron or the mixtures or alloys thereof. The coating formed as a thin layer is applied preferably onto a rough substrate surface whose roughness is characterized by a random distribution of the deviations from the mean level and the standard deviation of this distribution ranges from 0 to 1500 nm, preferably 40 to 120 nm.

The coating may additionally be coated with at least one further thin layer selected from the group consisting of one or more oxides, preferably SiO₂, TiO₂, ZrO₂, HfO₂, Al₂O₃, Y₂O₃, niobium, molybdenum, tungsten and tantalum oxides.

In a preferred embodiment, an intermediate layer producing adhesive strength is provided between the substrate and the coating. This intermediate layer comprises a metal, preferably chromium, copper, nickel, molybdenum, tantalum, niobium, silver or alloys of these metals, or a semiconductor.

Growth of endogenous cells, which serves particularly for anchoring the implant but also for inducing the formation of a physiological surface, can be controlled by the composition of the material surface. The surface coating can be applied to many different basic materials (substrates), e.g. metals and plastics, having differing geometry. A special advantage of the implants according to the invention is represented by the cost-effective production as well as the fact that as a function of the chosen method the coating can also be applied to materials which do not tolerate heating because of their special structure.

The coating can be made by means of both the CVD method and the PVD method, but especially preferably by the PVD method. In particular, the following process is suited for the production of the implants according to the invention: While the metal of group IVA of the periodic table is deposited onto a substrate suitable as an implant, an oxide, nitride or carbide compound forms by maintaining a gas atmosphere which contains at least one of the gases N₂, O₂, CH₄ and/or noble gases. In this connection, the condensation of the metal particles on a heatable or coolable substrate is controlled via the total gas pressure P_{tot} , the deposition rate r , the substrate temperature T_{sub} and by the distance l existing between metal source and substrate, such that the volume fraction of voids is 2 to 45% by volume, whose sizes range from (0.4 nm)³ to (50 nm)³. The production parameters are chosen as follows:

$T_{sub} = -5$ to 400°C ,

$l = 0.01$ to 1.5 m

the partial pressure ratio of the introduced gases N₂ and O₂:

$(P_{N_2}/P_{O_2}) = 1$ to 2000 ,

$P_{tot} = 2 \times 10^{-5} \text{ hPa} - 4 \times 10^{-2} \text{ hPa}$ and

$r = 0.01$ to 60 nanometers/s .

For the production process it is necessary to adjust the production parameters such that the portion of voids is foreseeable. This can be done by the following procedure: the following applies to substrate temperatures ranging from preferably 100 to 220°C and a distance of the vapor source to the substrate l ranging preferably from 0.5 to 1.2 m :

A volume fraction of 34% of voids will be achieved if

$$K = P_{tot} \cdot r / l = (1 \text{ to } 3) \cdot 10^{-4} \frac{\text{mBar nm}}{\text{sm}}$$

and the total gas pressure P_{tot} ranges from $0.7 \times 10^{-3} \text{ hPa}$ to $2 \times 10^{-2} \text{ hPa}$.

A volume fraction of 20% of voids is achieved when a choice is made within the range of

$$K = P_{tot} \cdot r / l = (0.2 \text{ to } 0.5) \cdot 10^{-4} \frac{\text{mBar nm}}{\text{sm}}$$

Volume fractions between 20 and 34% may be adjusted by choosing the magnitude K according to the following equation:

$$K = ((0.04 \text{ to } 0.2) \cdot \text{desired void portion} - 0.7) \cdot 10^{-4} \frac{\text{mBar nm}}{\text{sm}}$$

Thus, there is the possibility of producing the desired void portion in the material according to the invention by adjusting rate r , the total gas pressure P_{tot} and the distance l .

By analogy, the volume fraction of the voids in the layer can be controlled for the substrate temperatures ranging from preferably 250 to 400°C and l ranging from preferably 0.5 to 1.2 m as follows: A volume fraction of e.g. 40% of voids will be achieved if

$$K = (6 \text{ to } 8) \cdot 10^{-4} \frac{\text{mBar nm}}{\text{sm}}$$

and P_{tot} ranges from $2 \times 10^{-2} \text{ hPa}$ to $4 \times 10^{-2} \text{ hPa}$. If K is chosen within the range of

$$K = (0.8 \text{ to } 1.9) \cdot 10^{-4} \frac{\text{mBar nm}}{\text{sm}},$$

the volume fraction of the voids will be 20%. In order to realize values between 20 and 40% of volume fractions, K has to be chosen according to the equation:

$$K = ((0.12 \text{ to } 0.31) \cdot \text{desired void portion} - 0.4) \cdot 10^{-4} \frac{\text{mBar nm}}{\text{sm}}.$$

Volume fractions therebetween can be determined by linear interpolation in each case. Small volume fractions of voids (2–20%) are achieved with small rates of 0.01–0.1 nm/s and at low gas pressures of 10^{-4} – 2×10^{-4} mBar. Very large void portions (>40%) are achieved at high total gas pressures of $>4 \times 10^{-2}$ mbar: At these gas pressures, the material may be present as a loose compound. The coating is effected on a substrate which is suited as an implant as defined above.

In the case of plastic implants T_{sub} must, of course, be chosen such that plastics do not change, i.e. T_{sub} should be preferably 5 to 20 Kelvin below the transformation temperature of the plastics.

The coating is deposited on the substrate in a usual vacuum deposition apparatus as is common to a person skilled in this field.

As compared to the formerly used materials, the advantage of the coating material of the present invention consists particularly in that it is possible to vary between differing states (metallic, dielectric). As a result, the composition of the material can be adjusted such that it may have attracting or repelling properties for body cells, blood protein components or microorganisms.

The material has a portion of voids whose volume fraction may be increased or lowered as desired. By the void portion, the band structure can be adapted to the demands without changing the chemical composition. Thus, the positive properties of the coating material are lost very rapidly when the void size is above $(50 \text{ nm})^3$. In addition, the growth or adhering of living cells can be increased or decreased by the well-calculated selection of the void portion. In this connection, it is preferred that in addition to the above-described voids ranging from $(0.4 \text{ nm})^3$ to $(50 \text{ nm})^3$ the coating also contains greater voids above $(500 \text{ nm})^3$. This supports the growth of the implant in given cell structures or also the growth of cells onto the coated surface. This is supported by the fact that the implant material to be coated (i.e. the substrate) may have a rough surface. The surface roughness is preferably between 0–1500 μm .

Another advantage is that the material can be supplied with depot substances, preferably coagulation-inhibiting substances or antibiotics, which are then continuously released from the material.

The surface coating of the implant according to the invention is especially advantageous because the described material has a conductivity which prevents the formation of volume charges activating fibrinogen. In addition, the described coating material has an electron density which does not permit a space current from fibrinogen to the implant. This property also prevents the activation of fibrinogen. These positive properties of the described material are adjusted in two ways: on the one hand, by varying the voids within the claimed range and, on the other hand, by varying the chemical composition. Both possibilities serve for achieving that the electron density of the coating is

on the energetic level of the protein states in the blood. In addition, it is beneficial that the coating be developed in such a way that the charge exchange processes occurring between the coagulation-specific proteins and the implant surface are prevented.

The implant can be used for implantation or short-term or long-term introduction into or attachment to the animal or human body.

The invention is now described in more detail with reference to the figures:

FIG. 1 shows a section through the coating of an implant

FIG. 2 shows UPS spectra of six coatings of endotracheal tubes

FIG. 3 shows contact angle pictures of 3 modifications of TiN_xO_y (wherein $x=1.0$ and $y=1.1$, but the void portions vary) relative to water. In (a), the void portion is 40%, in (b), it is 22%, and in (c), it is 3%. The adhesive properties are controlled by the void portion.

The invention is now described in more detail with reference to the examples:

EXAMPLES

Example 1

The surface of a heart valve prosthesis made of the basic material titanium was coated with a coating of TiN_xO_y ($x=1.2$ and $y=0.6$; measured by means of Elastic Recoil Detection (ERD)). The coating was produced by means of reactive evaporation with selection of the following parameters: substrate temperature= 250°C ., distance between evaporator and substrate= 45 cm ; partial pressure ratio (N_2 to O_2)= 1500 ; total pressure= $7 \times 10^{-4} \text{ hPa}$; deposition rate= 0.2 nm/s .

The void portion in the coating material was around 28% and the void size was between $(0.6 \text{ nm})^3$ and $(0.9 \text{ nm})^3$.

FIG. 1 shows a section through the coated heart valve prosthesis, (1) representing the surface of the basic material and (2) denoting the coating. The coating (2) has a thickness of $3 \mu\text{m}$.

Example 2

Six endotracheal tubes were coated. The coating was produced by means of reactive evaporation with selection of the following parameters: substrate temperature= 250°C ., distance between evaporator (metal source) and substrate 45 cm ; total pressure= $7 \times 10^{-4} \text{ hPa}$; deposition rate= 0.2 nm/s . The partial pressure ratio (N_2 to O_2) of the supplied gas es was varied.

The void portion in the coating material was around 24%, and the void size was between $(0.6 \text{ nm})^3$ and $(0.9 \text{ nm})^3$.

UPS spectra which are shown in FIG. 2 were made of the six coatings.

Graph (1): Coating of TiN_xO_y wherein $x=0.5$ and $y=1.4$, measured by means of Elastic Recoil Detection (ERD). The partial pressure ratio (N_2 to O_2) was 120.

Graph (2): Coating of TiN_xO_y wherein $x=0.9$ and $y=1.2$, measured by means of Elastic Recoil Detection (ERD). The partial pressure ratio (N_2 to O_2) was 500.

Graph (3): Coating of TiN_xO_y wherein $x=0.9$ and $y=0.8$, measured by means of Elastic Recoil Detection (ERD). The partial pressure ratio (N_2 to O_2) was 900.

Graph (4): Coating of TiN_xO_y wherein $x=0.9$ and $y=0.2$, measured by means of Elastic Recoil Detection (ERD) The partial pressure ratio (N_2 to O_2) was 1200.

Graph (5): Coating of TiN_xO_y wherein $x=1.4$ and $y=0.3$, measured by means of Elastic Recoil Detection (ERD) The partial pressure ratio (N_2 to O_2) was 1600.

Graph (6): Coating of TiN_xO_y wherein $x=1.5$ and $y=0.15$, measured by means of Elastic Recoil Detection (ERD) The partial pressure ratio (N_2 to O_2) was 2000.

The coatings on which graphs (2) to (6) are based markedly show a Fermi level which is correlated with conductivity.

Example 3

Three differing coating materials of TiN_xO_y ($x=1.0$, $y=1.1$) were applied by means of vacuum deposition onto endotracheal tubes and contact angle pictures of the three coatings were made. The results are shown in FIG. 3. (a) is the picture of a sample having a 40% void portion, (b) is that of a sample having a 22% void portion, and (c) is that of a sample having a 3% void portion.

The parameters chosen for the production of the coating were:

in the sample having 40% of void portion :

distance between metal source and substrate=70 cm

substrate temperature $T_{\text{sub}}=300^\circ\text{C}$.

partial pressure ratio ($P_{\text{N}_2}/P_{\text{O}_2}$)=1200

deposition rate $r=0.01\text{ nm/s}$

total gas pressure= $2\times 10^{-2}\text{ hPa}$

A void size between $(0.8\text{ nm})^3$ and $(2.8\text{ nm})^3$ resulted.

in the sample having a void portion of 22%:

distance between metal source and substrate=70 cm

substrate temperature $T_{\text{sub}}=300^\circ\text{C}$.

partial pressure ratio ($P_{\text{N}_2}/P_{\text{O}_2}$)=1200

deposition rate $r=0.25\text{ nm/s}$

total gas pressure= $2\times 10^{-4}\text{ hPa}$

A void size between $(0.6\text{ nm})^3$ and $(0.9\text{ nm})^3$ resulted.

in the sample having a void portion of 3%:

distance between metal source and substrate=70 cm

substrate temperature $T_{\text{sub}}=300^\circ\text{C}$.

partial pressure ratio ($P_{\text{N}_2}/P_{\text{O}_2}$)=1200

deposition rate $r=0.7\text{ nm/s}$

total gas press= $2\times 10^{-4}\text{ hPa}$

A void size between $(0.4\text{ nm})^3$ and $(0.8\text{ nm})^3$ resulted.

As follows from FIG. 3, the adhesive properties of the coating can be controlled by varying the void portion.

What is claimed is:

1. An implant, comprising a substrate coated with a thin layer of a coating material, wherein said coating material comprises one or more metals (M) of group IV A of the periodic table, nitrogen (N) and oxygen (O), and wherein 2 to 45% of the volume in the coating material is formed by voids whose sizes range from $(0.4\text{ nm})^3$ to $(50\text{ nm})^3$ and the remaining volume comprises a composition of a metal of group IV A of the periodic table, nitrogen and oxygen in a ratio of 1:(0.1 to 1.7):(0.1 to 1.7), such that a material having the formula MN_xO_y wherein $x,y=0.1-1.7$ results.

2. The implant according to claim 1, wherein the coating material further comprises one or more of the following chemical compounds:

MN_x wherein $x=0.7$ to 1.2

MO_x wherein $x=0.7$ to 1.2

Magnelli phases of the M—O system ($\text{M}_n\text{O}_{2n-1}$)

MO_2

M_2N

wherein M is a metal of group IV A of the periodic table.

3. The implant according to any one of claims 1 to 2, wherein the coating material contains small amounts of carbon compounds of a metal of group IV A of the periodic table.

4. The implant according to any one of claim 1 or 2, wherein the metals (M) of group IV A of the periodic table, nitrogen (N) and oxygen (O) may occur in the coating material in crystalline or amorphous form.

5. The implant according to any one of claim 1 or 2, wherein the real part of the refractive index of the coating material for the X-ray wavelength of 0.0709 nm ranges from 0.9999984 to 0.9999973.

6. The implant according to any one of claim 1 or 2, wherein the mass density of the coating material ranges from 3.5 to 5.4 g/cm^3 .

7. The implant according to any one of claim 1 or 2, further comprising at least one compound selected from the group consisting of niobium, tantalum, tungsten, molybdenum and alloys thereof.

8. The implant according to any of claim 1 or 2, wherein the coating material further comprises hydrogen.

9. The implant according to any one of claim 1 or 2, wherein the layer thickness of the coating material on the substrate ranges from 3 nm to 3 mm.

10. The implant according to any one of claim 1 or 2, wherein the specific resistance ranges from 30 to 300000 $\mu\Omega\text{cm}$.

11. The implant according to any of claim 1 or 1, wherein the coating material is applied as a thin layer onto a rough substrate surface wherein the roughness is characterized by a random distribution of deviations from a mean level wherein a standard deviation of the distribution ranges from 0 to 1500 μm .

12. The implant according to any one of claim 1 or 2, wherein the thin coating layer is coated with at least one further thin layer comprising one or more oxides selected from the group consisting of SiO_2 , TiO_2 , ZrO_2 , HfO_2 , Al_2O_3 , Y_2O_3 , niobium oxide molybdenum oxide, tungsten oxide and tantalum oxide.

13. The implant according to any one of claim 1 or 2, wherein at least one further thin layer, made of a metal or a semi-conductor is introduced between the substrate and the coating.

14. The implant according to any one of claim 1 or 2, wherein the coating material is applied onto a metallic substrate comprising molybdenum, silver, gold, copper, aluminum, tungsten, nickel, chromium, zirconium, titanium, hafnium, tantalum, niobium, vanadium, iron and one or more alloys thereof.

15. The implant according to any one of claim 1 or 2, wherein the coating material is applied onto a plastics substrate comprising a polyester, a polyamide, a polyurethane (PUR), a polyethylene (PE), a polytetrafluoroethylene (PTFE) or DACRON^R.

16. The implant according to any one of claim 1 or 2, wherein the voids range from $(0.4\text{ nm})^3$ to $(50\text{ nm})^3$ and the coating material has voids greater than $(500\text{ nm})^3$.

* * * * *

EVIDENCE APPENDIX B

Development of an energetic ion assisted mixing and deposition process for TiN_x and diamondlike carbon films, using a co-axial geometry in plasma source ion implantation

Shamim M. Malik,^{a)} R. P. Fetherston, and J. R. Conrad

Department of Nuclear Engineering and Engineering Physics, University of Wisconsin, Madison, Wisconsin 53706

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Plasma source ion implantation (PSII) is a relatively simple technique for the ion implantation/deposition of materials. In PSII a substrate is immersed in a plasma, and high negative voltage pulses are applied to accelerate ions into the substrate resulting in modification of the properties of the material in the near surface region. A technique was developed to produce uniform diamondlike carbon coatings and TiN_x films inside and outside a hollow cylinder (substrate). A description of apparatus, experimental methods for this type of deposition process, and preliminary results are presented in this article. © 1997 American Vacuum Society. [S0734-2101(97)03206-5]

I. INTRODUCTION

Plasma source ion implantation (PSII)¹⁻⁴ is a relatively simple ion implantation/deposition technique for the surface modification of materials for tribological and semiconductor applications. In PSII, a substrate is immersed in a plasma and a train of high negative voltage pulses is applied to the substrate. When negative high voltage pulses are applied to the substrate, a region of high electric field is formed inside the plasma sheath. The ions accelerate under the influence of electric field inside the sheath. Hence, the desired ion species are injected into the substrate to modify the properties of the material in the near surface region. The PSII technique has been used to implant nitrogen, oxygen, carbon, and boron ions into various materials. PSII has been applied to tailor the surface properties of materials for wear, corrosion, friction, and hardness improvements.⁵

Besides ion implantation, the PSII has been also used to mix the films deposited by sputtering of various materials such as titanium, tantalum, and chromium. Conventionally, the acronyms used to describe the sputter deposition and mixing processes used to produce these films: Ion beam assisted deposition (IBAD), ion beam enhanced deposition (IBED), ion assisted deposition (IAD), etc. Because in the case of PSII-based deposition there is no beam of ions involved, these acronyms do not accurately describe the process. However, the PSII based deposition process is better represented using a term such as energetic ion assisted mixing and deposition (EIAMAD). The advantage of the PSII-EIAMAD process over conventional beam line ion beam enhanced deposition (IBED) is that in PSII-EIAMAD energetic ions are accelerated in the gap between the sputtering cathode and the entire surface of the substrate, while in IBED the substrate has to be manipulated and the ion beam needs rastering. Figure 1 represents a schematic of a PSII-EIAMAD process. In this setup the sputtering cathode (target) is powered by radio frequency (rf) source which produces a nega-

tive self-bias on the cathode. The cathode (target) can also be negatively biased by a direct current (dc) voltage or combination of both the dc and the rf. The material sputtered from the cathode (target) deposits on the substrate which is biased with a train of negative dc high voltage pulses. There is a mixture of nitrogen and argon plasmas between the sputtering cathode and the substrate. The nitrogen ions form compound with the sputtered material e.g., Ti, Cr, and Ta, while the argon ions play double role; (i) sputtering from the cathode and (ii) mixing on the substrate. A conceptual representation of this process has been depicted in Fig. 1. We have employed the PSII-EIAMAD process to produce hard coatings of golden color titanium nitride (TiN_x), golden brown color chromium nitride (CrN), and shiny translucent diamondlike carbon (DLC) films. Figure 2 represents an example of Auger profile of atomic concentration of CrN deposited by the PSII-EIAMAD process as shown in Fig. 1. A chromium plated copper plate was used as the sputtering cathode (target) and rf power of 400 W was applied to it. The partial pressure of argon and nitrogen was maintained at 1 mTorr for each of the two gases. The substrate was biased at 24 kV, 100 Hz, with a 20 μs of pulse width. We have also produced silver gray TaN using the scheme shown in Fig. 1; the detailed results are discussed somewhere else.⁶ The microstructural properties of the coated films can be tailored by varying the pulse width and frequency of the applied voltage pulses during deposition.

In order to prepare the surface of the substrate for PSII processing, contaminants and oxide layers are removed by sputtering the surface using energetic ions from argon plasma. Plasma cleaning is desirable for good adhesion of the deposited films and prevention of cross-implantation. The substrate surface is precleaned chemically and then *in situ* sputtering is performed before the PSII process is applied. Argon plasma is used to sputter clean the substrate surface. Typical processing parameters applied for surface cleaning of the substrate are; (i) argon gas pressure on the order of 1 mTorr, (ii) ion dose $\sim 1 \times 10^{17}$ ions- cm^{-2} and, (iii) substrate bias $\sim 2-10$ kV.

^{a)}Electronic mail: shamim@engr.wisc.edu

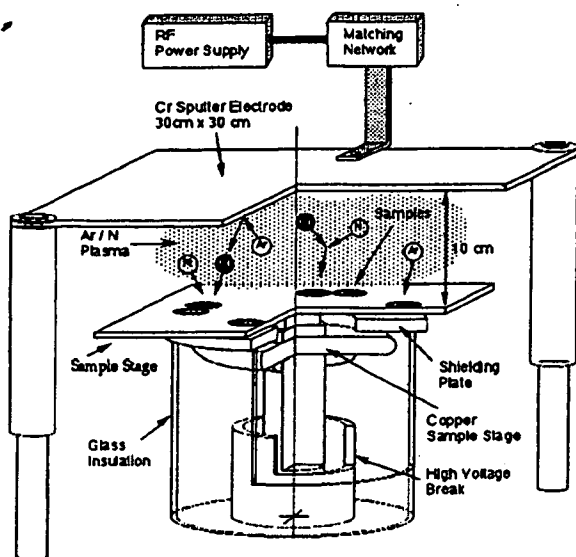


FIG. 1. Experimental setup used for producing PSII-EIAMAD coatings, e.g., TiN_x , CrN , and TaN on planar samples.

PSII-EIAMAD compound films are produced using a sputter cathode (target) of the corresponding metal and a mixture of reactive gas and an argon plasma. A sputtering cathode (target) is installed conformal to the surface of the substrate. A mixture of an inert gas and a reactive gas is introduced in the vacuum chamber to generate a plasma. Typically argon, neon, or krypton are the inert gases and nitrogen, methane, oxygen are reactive gases. A heavier gas like Kr is used to enhance mixing but a lighter gas like Ne is desirable if surface damage is a concern. After sputter cleaning, the substrate may be implanted with a relevant ion species for improved adhesion. A negative dc-bias or rf self-bias is applied to the sputter cathode (target). The positive ions of an inert gas impinge on the surface of the target and knock off the target atoms and these atoms are deposited on the surface of the substrate. The right combination of gases is chosen for mixing and the production of stoichiometric films; e.g., a 6% nitrogen and 94% argon mixture with tita-

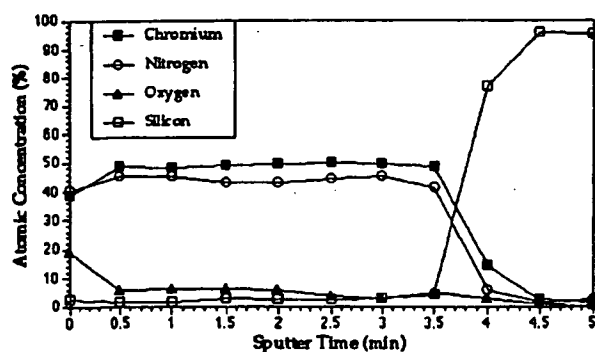


FIG. 2. Auger profile of CrN deposited on silicon samples using experimental setup shown in Fig. 1.

nium as the sputtering cathode (target) has produced films of golden-colored, nearly stoichiometric TiN_x films.

DLC films are also produced using PSII-EIAMAD in which methane and/or acetylene (C_2H_2) plasmas are applied. When high voltage pulses are applied to the substrate immersed in a neutral gas at high pressure (order of a mTorr), a plasma is generated by the glow discharge (GD) phenomenon. The DLC films were characterized using Raman spectroscopy and high quality films have been produced using this method.^{7,8} The DLC films have good adhesion, low friction, and enhanced wear resistance.

The purpose of this study was to use the PSII-EIAMAD technique to deposit films on the inside and outside of the cylindrical surfaces. In order to produce uniform ion implantation, and PSII-EIAMAD on the inner surface of a cylindrical substrate a co-axial configuration was adopted. When an anode is placed inside the cylinder (substrate) and it is biased at a negative high voltage potential, a uniform radial electric field normal to the inner surface of the cylinder (substrate) is generated. A plasma can be generated inside the cylinder (substrate) due to a glow discharge phenomena. We have performed two sets of experiments for cylindrical substrates. In one set of experiments the uniformity of DLC films on the outer surface of a cylinder (substrate) (6.35 cm diam and 12.7 cm high) was evaluated. In other set of experiments DLC and TiN_x films were produced on the inner surface of a cylindrical substrate. In our first experiment DLC films were produced on the outer surface of a cylinder (substrate) without a co-axial geometry configuration. The DLC films produced were nonuniform and also a significant amount of yellowish gray coating was observed on the walls of the vacuum chamber. In a second experiment, a co-axial geometry was used to resolve three issues; (1) production of uniform discharge surrounding the substrate for better uniformity of DLC films, (2) eliminating deposition, on the chamber walls, (3) evaluation for multicomponent batch processing to understand scale-up possibilities. In a third experiment the PSII-EIAMAD technique was used on the inner surface of a cylinder (substrate) with $ID=8.9$ cm and length=60 cm and TiN_x films were deposited on the inner surface of the cylindrical substrate. In a fourth experiment DLC films were produced on the inner surface of the cylindrical substrate. The uniformity of these films has been evaluated and will be presented in this article.

II. EXPERIMENTAL METHODS AND PROCESSING PARAMETERS

Figure 3 shows a systematic diagram for the production of DLC films on the outer surface of a cylindrical substrate. The experimental setup was arranged in a cylindrical vacuum chamber. A detailed description of the PSII system has been described elsewhere.¹⁻⁴ In this experimental setup, a cylindrical substrate of 6.35 cm diam and 12.7 cm high was placed on a high voltage feedthrough inside the PSII vacuum chamber. The cylinder (substrate) was surrounded by an aluminum tube as a co-axial configuration. The surrounding aluminum tube was kept at ground potential in order to provide

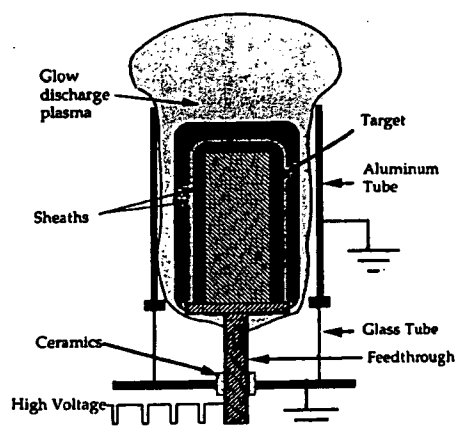


FIG. 3. Experimental setup used for producing DLC films on the outer surface of a cylinder.

a uniform electric field distribution on the surface of the substrate. The PSII chamber was pumped to a base pressure on the order of 10^{-7} Torr and argon gas was injected into the chamber and a pressure of 10 mTorr was established. A glow discharge plasma was generated in between the cylinder (substrate) and the aluminum tube using a train of negative high voltage pulses applied to the substrate. The substrate was sputter cleaned by applying a dose of 1×10^{17} ions- cm^{-2} . In order to establish good adhesion of the DLC films on the surface of the substrate, a methane plasma was used to implant the carbon ions. After surface preparation of the substrate, the acetylene gas was used to produce DLC films. In this case the ion energy was 5 keV, pulse width 100 s, frequency 100 Hz, and acetylene pressure was 50 mTorr. Prior to this experiment, DLC films were produced on the surface of the same cylinder (substrate) without the aluminum tube housing and as a result a nonuniform DLC film were observed on the cylinder (substrate). There was also a significant quantity of yellowish-gray dust on the surface of the chamber wall produced during the DLC production. To alleviate these problems an aluminum tube was used as a housing to surround the substrate and was held at ground potential.

A set of twelve silicon samples was affixed on the surface of the substrate at four circumferential points at three locations along the length for postprocess analysis. In order to measure the deposited film thickness the silicon samples were partly masked. The uniformity was measured on the outer surface of a cylinder (substrate), the silicon samples were removed from the substrate surface, and then the masks were removed from the silicon samples. Surface profilometry was used to measure the thickness of the TiN_x and DLC films.

Figure 4 shows a setup for the processing on the inner surface of a cylindrical substrate. A cylindrical substrate was supported by ceramic stands and the central electrode was separately supported with ceramic stands. The electrical connections were made using two feedthroughs for rf power and a high voltage feedthrough for the substrate. The important

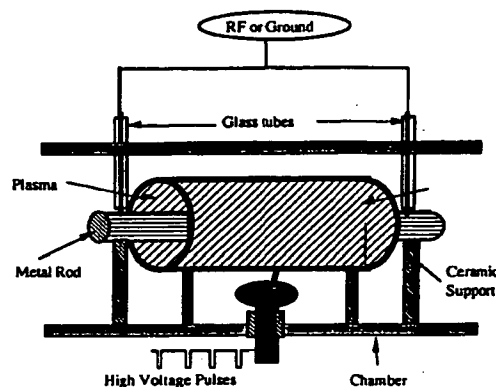


FIG. 4. Experimental setup used for producing DLC films on the inner surface of a cylinder.

concept for production of films inside a cylindrical substrate was using a co-axial configuration, in which the central electrode was kept at rf bias or ground potential. The central electrode was used as rf antenna and also as sputtering cathode. The rf was applied to the antenna (central electrode of the co-axial geometry) through a matching network. The outer cylinder (substrate) was pulsed to high voltage for PSII-EIAMAD and precleaning. A titanium rod was used for the central sputtering cathode (target) and TiN_x films were produced on the inner surface of the cylinder (substrate) by applying a PSII-EIAMAD process. Acetylene gas was used for DLC films and a mixture of nitrogen (6%) and argon (94%) was used to produce nitrides coatings. It was experimentally determined that the geometry of central electrode is crucial for generation of plasma at the proper position. A solid rod (target) as a central electrode produced a uniform plasma in between the target and outer cylinder (substrate). The argon pressure was in the range of 2–100 mTorr, and rf power 400 W. When a hollow tube (target) was used as central electrode (rf antenna) the plasma was more intense inside the rf antenna as compared to its outer surface. However, it was possible to enhance plasma outside the central tube (rf antenna and sputter target) by increasing pressure above 10 mTorr. Concurrently, the plasma was also enhanced inside the antenna tube (target).

III. RESULTS AND DISCUSSIONS

The goal of the co-axial experiment was to demonstrate that the PSII based sputter deposition and mixing process, i.e., PSIII-EIAMAD could be used for the production of DLC films on the outer and the inner surface of a cylindrical substrate. We have discussed the concept and experimental setup in the previous sections.

Figure 5 represents the circumferential and longitudinal film thickness on the outer surface of the cylinder (substrate). The DLC films were adherent to the surface of the substrate. Figure 5 shows the film thickness of DLC which is $\sim 1 \mu\text{m}$ and with variations of about 100 Å. These variations might be caused by sample fixations and masking effects.

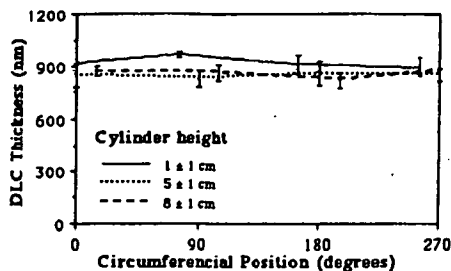


FIG. 5. Thickness of DLC films on the outer surface of the cylinder (substrate).

We have been able to produce the DLC films at deposition rate of $\sim 1 \mu\text{m/h}$. It has been determined that films were strongly bonded and adhesion strength was on the order 7 kpsi for aluminum based materials.

Figure 6 represents the dimensions of the hollow cylinder (substrate) which was used for DLC and TiN_x films on its inner surface. In order to produce DLC films, the central cylinder was kept electrically at ground potential so that a glow discharge is produced uniformly along the length of the substrate. Figure 7 shows the longitudinal and circumferential distribution of DLC films on the inside surface of the substrate shown in Fig. 6. The uniformity of the film thickness was within 30% accuracy along the length of the cylinder (substrate), and the uniformity of the film thickness was within 5% accuracy along the circumference of the cylinder (substrate) at five different positions along the length of the cylinder. The variations along the length of the cylinder might be due to nonuniformity of plasma generation inside the cylinder due to electric field distribution and the plasma variation might also be due to gas distribution. Figure 7 shows the uniformity of the TiN_x films inside the surface of the cylinder. In order to produce TiN_x , rf was applied to the central titanium rod to produce plasma. In this case 94% argon and 6% nitrogen was used as source gas. Argon sputters titanium atoms from the rod and also mixes TiN_x films on the inner surface of the cylinder. Figure 7 shows the uniformity of TiN_x films along the length of the cylinder at four

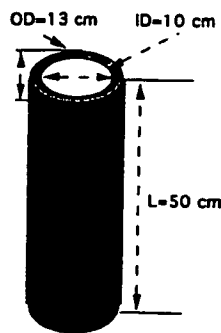


FIG. 6. Dimensions of hollow cylinder (substrate) for DLC and TiN_x coatings on its inner surface.

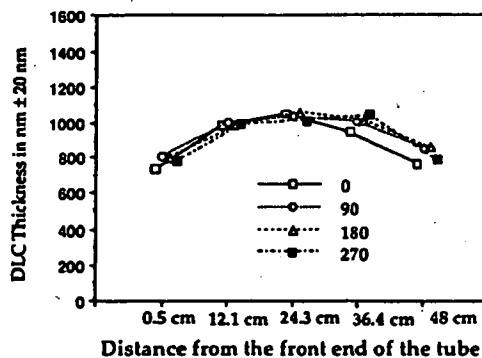


FIG. 7. Thickness of DLC films on the inner surface of the cylinder (substrate).

positions. If we compare the uniformity of DLC and TiN_x (Figs. 7 and 8) we notice that the deposition rate decreases for DLC from the longitudinal center to ends of the cylinder, but in the case of TiN_x films the deposition rate increases. The aforementioned difference could be due to a dc glow discharge versus rf discharge plasmas. The glow discharge is produced due to bias on the cylinder and we expect more uniform distribution of the plasma inside the cylinder because of the co-axial ground. One possible explanation might be that there is more residual time for carbon ions at the center of the cylinder as compared to the ends. In the case of rf plasma generation the rf power was applied from the ends of the rod using a split feedthrough so we might have the gradual decrease in the transmission of rf power, which along the length of the electrode. So less rf power might generate less plasma density, and hence less TiN_x film thickness. Overall, the film thickness uniformity appear reasonable for tribological applications.

IV. SUMMARY

In this study we have demonstrated a method to deposit DLC and TiN_x films on inside surface of a hollow cylinder

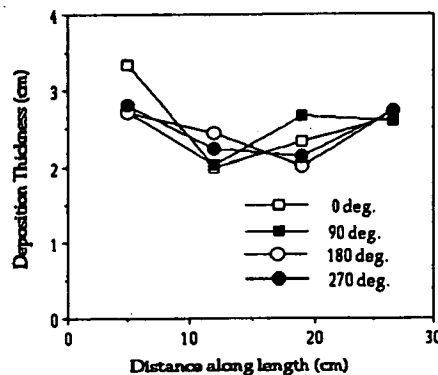


FIG. 8. Thickness of TiN_x films on the inner surface of the cylinder (substrate).

and also on the outside surface of a solid cylinder. A co-axial configuration was used to produce these coatings. PSII was applied to EIAMAD of the films. TiN_x films were produced on the inside surface of a hollow cylinder. The coatings are adherent and reasonably uniform over the surface.

ACKNOWLEDGMENTS

The authors are grateful to Dr. J. Moriarty and Dr. R. Kalkan at Rock Island, Arsenal, IL for providing the application cylinder and useful collaborations with our group. We would also like to acknowledge useful discussions with Dr. Kumar Sridharan and administrative support from John Doyle. This work was supported by U.S. Army Grant No. DAAH04-94-6-0283.

¹J. R. Conrad, U.S. Patent No. 4 764 394 (16 August 1988).

²S. M. Malik, K. Sridharan, R. P. Fetherston, A. Chen, and J. R. Conrad, *J. Vac. Sci. Technol. B* **12**, 843 (1994).

³S. M. Malik, J. T. Scheuer, and J. R. Conrad, *J. Appl. Phys.* **69**, 2904 (1991).

⁴J. R. Conrad, R. A. Dodd, S. Han, M. Madapura, J. Scheuer, and K. Sridharan, *J. Vac. Sci. Technol. A* **3146**, (1990).

⁵J. R. Conrad, A. Chen, R. A. Dodd, J. T. Scheuer, K. Sridharan, and F. J. Worzala, *Surface Modification of Materials by Plasma Source Ion Implantation*, Proc. ASM-TMS, New Orleans, LA, Feb. 1991, Plasma and Laser Processing of Materials, edited by Upadhyaya, pp. 141-149.

⁶K. C. Walter, R. P. Fetherston, K. Sridharan, A. Chen, M. M. Shamim, and J. R. Conrad, *Mater. Res. Bull.* **29**, 827 (1994).

⁷J. Chen, L. Xie, J. R. Conrad, and R. A. Dodd, *J. Mater. Eng. Performance* **2**, 839 (1993).

⁸L. Xie, F. J. Worzala, J. R. Conrad, and R. A. Dodd, *Materials Week '92* Chicago, IL. 2-5 November 1992.

EVIDENCE APPENDIX C



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/997,450

11/30/2001

Shamim M. Malik

50623.061

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45159 7590 05/12/2009
SQUIRE, SANDERS & DEMPSEY LLP
1 MARITIME PLAZA
SUITE 300
SAN FRANCISCO, CA 94111

EXAMINER

SEVERSON, RYAN J

ART UNIT

PAPER NUMBER

3731

MAIL DATE

DELIVERY MODE

05/12/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/997,450	Applicant(s) MALIK ET AL.	
	Examiner Ryan J. Severson	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 13, 14, 17-19, 21, 24-27, 34 and 42-45 is/are pending in the application.
- 4a) Of the above claim(s) 1, 7-10, 13, 14, 17, 18, 26, 27, 34 and 42-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-6, 19, 21, 24 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. **Claims 2-6, 19, 21, 24, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lazarov et al. (6,110,204) in view of Shamim M. Malik et al.**

("Development of an energetic ion assisted mixing and deposition process for TiN_x and diamondlike carbon films, using a co-axial geometry in plasma source ion implantation"). Lazarov reference discloses the titanium-nitride-oxide (TiN_xO_y) compound disposed about a stent substrate substantially as claimed. However, Lazarov reference does not disclose the compound is implanted on a molecular level within the surface of the stent. Attention is drawn to Malik et al., who teach implantation of various compounds (including Ti, N, and O) within the surface of a metallic substrate to increase the ability of the compound to adhere to the substrate. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have implanted the compound of Lazarov within the surface of the stent, as taught by Malik et al., to increase the adhesion between the compound and the substrate (the stent).

3. Regarding claim 24, it is well-known in the art to use stainless steel as a material to make stents.

.Response to Arguments

4. Applicant's arguments filed 24 February 2009 have been fully considered but they are not persuasive. Applicant argues the combination is improper because Malik teaches the concept of ion implantation, but does not teach implantation of Ti or its alloys. However, Malik was not relied upon for teaching implantation of the entire alloy. Malik was used to show that ion implantation with materials similar or the same as those in the alloy can be implanted at a depth within the surface of the stent. Further, the claims only require the Ti or N to be implanted within the surface of the stent. Malik clearly teaches implantation of nitrogen (N) compounded with titanium (Ti) in the surface, as claimed. Further, Lazarov teaches layering TiN_xO_y . Therefore, the totality of evidence shows that it is known in the art to implant TiN in the surface of a stent, and to have a covering of TiN_xO_y over the surface of the stent. It is the Examiner's position that one of ordinary skill in the art at the time the invention was made would have found it obvious to combine the teachings of Lazarov and Malik to reach the claimed invention.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

6. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

Art Unit: 3731

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ryan J. Severson whose telephone number is (571) 272-3142. The examiner can normally be reached on Monday - Friday 8:30-5:00.

8. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

9. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. J. S./
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
5/11/09

EVIDENCE APPENDIX D



UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/997,450

11/30/2001

Shamim M. Malik

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SQUIRE, SANDERS & DEMPSEY LLP
1 MARITIME PLAZA
SUITE 300
SAN FRANCISCO, CA 94111

EXAMINER

SEVERSON, RYAN J

ART UNIT

PAPER NUMBER

3731

MAIL DATE

DELIVERY MODE

07/09/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 09/997,450	Applicant(s) MALIK ET AL.	
	Examiner Ryan Severson	Art Unit 3731	

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- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 13, 14, 17-19, 21, 24-27, 34 and 42-45 is/are pending in the application.
- 4a) Of the above claim(s) 1, 7-10, 13, 14, 17, 18, 26, 27, 34 and 42-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-6, 19, 21, 24 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
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Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

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| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/24/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Claims 1, 7-10, 13, 14, 17, 18, 26, 27, 34, and 42-45 are directed to an invention that is independent or distinct from the invention elected in the response to restriction filed 06 July 2004. Accordingly, claim 1, 7-10, 13, 14, 17, 18, 26, 27, 34, and 42-45 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.
2. Specifically regarding claims 1 and 13, the claims recite, in the alternative, a compound of Ti, N, C, or Ti, N, O is implanted, then subsequently a layer of TiN_xC_y is disposed over the compound. As applicant is aware, claims are read in light of the specification. Upon reading the specification, it becomes clear that the layer of TiN_xC_y is only disposed over an implanted compound of Ti, N, C and not Ti, N, O. Therefore, since the specification provides no support for disposing a layer of TiN_xC_y over implanted Ti, N, O, the claims are interpreted as being drawn to the combination of the layer of TiN_xC_y disposed over implanted Ti, N, C. This combination was not elected in response to the restriction requirement and therefore claims 1 and 13 and all claims that depend therefrom are withdrawn from further consideration as being drawn to a non-elected invention.
3. Claims 2-6, 19, 21, 24, and 25 are the remaining claims that read on the elected invention and therefore have been examined on the merits.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. **Claims 2-6, 19, 21, 24, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lazarov et al. (6,110,204) in view of Shamim et al.**

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6. Regarding claim 24, it is well-known in the art to use stainless steel as a material to make stents.

Response to Arguments

7. Applicant's arguments with respect to claims 19 and 21 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

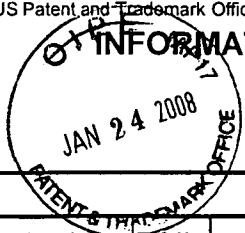
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ryan Severson whose telephone number is (571)272-3142. The examiner can normally be reached on Monday - Friday 8:30-5:00.

9. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. S./
Examiner, Art Unit 3731

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731

FORM PTO-1449 (Modified)		US DEPARTMENT OF COMMERCE		Docket No. 050623.61	Application No. 09/997,450
US Patent and Trademark Office		INFORMATION DISCLOSURE CITATION in an Application (Use several sheets if necessary)			
					
		Applicant Shamim Malik et al.		Filing Date November 30, 2001	Group Art Unit 3731

U.S. PATENT DOCUMENTS

Examiner Initial	Ref. No.	Document Number	Date of Patent	Name	Class	Subclass	Filing Date if Appropriate
/RS/	A1	4,486,247	12/4/84	Ecer et al.			
	A2	5,040,548	8/20/91	Yock			
	A3	5,047,050	9/10/91	Arpesani			
	A4	5,049,132	9/17/91	Shaffer et al.			
	A5	5,084,151	1/28/92	Vallana et al.			
	A6	5,165,919	11/24/92	Sasaki et al.			
	A7	5,192,311	3/9/93	King et al.			
	A8	5,188,734	12/23/93	Zepf			
	A9	5,415,704	5/16/95	Davidson			
	A10	5,925,552	7/20/99	Keogh et al.			
	A11	6,273,913	8/14/01	Wright et al.			
	A12	6,273,908	8/14/01	Ndondo-Lay			
	A13	6,335,029	1/1/02	Kamath et al.			
	A14	6,613,432	9/2/03	Zamora et al.			
	A15	7,056,523	6/6/06	Michal et al.			
	A16	7,077,860	7/18/06	Yan et al.			
	A17	7,163,165	1/16/07	Paul et al.			
↓	A18	7,163,715	1/16/07	Kramer			
/RS/	A19	7,201,940	4/10/07	Kramer			

U.S. PATENT APPLICATION DOCUMENTS

Examiner Initial	Ref. No.	Document Number	Filing Date	Name	Class	Subclass	Publication Date if Appropriate
/RS/	A20	09/997,449	11/30/01	Malik et al.			
/RS/	A21	10/672,890	9/26/03	Malik et al.			

U.S. PATENT APPLICATION PUBLICATION DOCUMENTS

Examiner Initial	Ref. No.	Document Number	Date of Publication	Name	Class	Subclass	Filing Date if Appropriate
/RS/	A22	20060178738	8/10/06	Yan et al.			
/RS/	A23	20070036905	2/15/07	Kramer			

/RS/	A24	20070166496	7/19/07	Kramer							
/RS/	A25	20070184228	8/9/07	Kramer							
FOREIGN PATENT DOCUMENTS											
Examiner	Ref. No.	Document	Date of	Country	Class	Subclass	Translation				
Initial		Number	Publication				Abstract				
							Yes	No			
/RS/	B1	DE 19855786	6/8/00	Germany			X				
	B2										
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)											
/RS/	C1	Malik et al., <i>Development of an Energetic Ion Assisted Mixing and Deposition Process for TIN_x and Diamondlike Carbon Films, Using a Co-axial Geometry in Plasma Source Ion Implantation</i> , J. Vac. Sci. Technol. A, Vol. 15, No. 6, pp. 2875-2879 (Nov./Dec. 1997).									
/RS/	C2	Malik et al., <i>Overview of plasma source ion implantation research at University of Wisconsin-Madison</i> , J. Vac. Sci. Technol. B, No. 12, Vol. 2, pp. 843-849 (Mar./Apr. 1994).									
/RS/	C3	Malik et al., <i>Sheath dynamics and dose analysis for planar targets in plasma source ion implantation</i> , Plasma Sources Sci. Technol. Vol. 2, pp. 81-85 (1993).									
/RS/	C4	Scheuer et al., <i>Model of plasma source ion implantation in planar, cylindrical, and spherical geometries</i> , J. Appl. Phys., Vol. 67, No. 3, pp. 1241-1245 (Feb. 1990).									
/RS/	C5	Shamim et al., <i>Measurement of electron emission due to energetic ion bombardment in plasma source ion implantation</i> , J. Appl. Phys., Vol. 70, No. 9, pp. 4756-4759 (Nov. 1991).									
/RS/	C6	Shamim et al., <i>Measurements of Spatial and Temporal Sheath Evolution for Spherical and Cylindrical Geometries in Plasma Source Ion Implantation</i> , J. Appl. Phys., Vol. 69, No. 5, pp. 2904-2908 (March 1991).									
EXAMINER				DATE CONSIDERED							
/Ryan Severson/				06/27/2008							
EXAMINER: Initial if references considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered.											
Include copy of this form with next communication to applicant.											

EVIDENCE APPENDIX E

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.: 09/997,450
Applicant: Shamim M. Malik
Filed: November 30, 2001
Art Unit: 3731
Examiner: Ryan J. Severson
Docket No.: 050623.00061
Confirmation No.: 3442
Customer No.: 45159
Title: A Modified Surface For An Implantable Device And A Method Of
Producing The Same

Mail Stop **Amendment**
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT

Sir:

In response to the Notice to Supply Omission of January 27, 2009, please consider the following:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 6 of this paper.

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings of the claims in the application:

Listing of Claims:

1. (Withdrawn and currently amended) A stent comprising a compound including Ti, N, C;
~~or including Ti, N, O, or both,~~ implanted on a molecular or atomic level at a depth within
at least a region of a surface of the stent and a layer of TiN_xC_y disposed over the
compound.
2. (Previously Presented) The stent of Claim 21, wherein x is 1 and y is 1 or 2.
3. (Previously Presented) The stent of Claim 21, wherein the depth of an implanted TiN_xO_y
compound is not greater than about 2000 Å from the surface of the stent.
4. (Previously Presented) The stent of Claim 21, wherein the layer of TiN_xO_y is exposed on
the surface of the stent.
5. (Original) The stent of Claim 4, wherein x is 1 and y is 1 or 2.
6. (Original) The stent of Claim 4, wherein the layer of TiN_xO_y compound is not more than
about 48,000 Å in thickness.
7. (Withdrawn) The stent of Claim 1, wherein the stent is made from stainless steel.
8. (Withdrawn) The stent of Claim 1, wherein the surface is the tissue-contacting surface of
the stent.

9. (Withdrawn) A stent comprising a layer of TiN_xC_y on a surface of the stent and a subsurface compound including Ti, N, or TiN disposed beneath the layer of TiN_xC_y , wherein the subsurface compound is intermixed with a surface material of the stent.
10. (Withdrawn) The stent of Claim 9, wherein a region of the layer of TiN_xC_y is implanted at a depth within a surface of the stent.
11. – 12. (Canceled)
13. (Withdrawn and currently amended) A method of modifying a surface of a stent, comprising implanting a compound including Ti, N, C, ~~or including Ti, N, O, or both~~, on a molecular or atomic level at a depth within a surface of the stent, followed by depositing TiN_xC_y over the implanted compound.
14. (Withdrawn) The method of Claim 13, wherein x is 1 and y is 1 or 2.
15. – 16. (Canceled)
17. (Withdrawn) The method of Claim 13, wherein the stent is made from stainless steel.
18. (Withdrawn and currently amended) The method of Claim 13, wherein prior to the act of implanting the compound including Ti, N, C, ~~or including Ti, N, O, or both~~, within the surface of the stent, the method comprises implanting Ti, N or TiN within the surface of the stent.

19. (Previously presented) A method of modifying a stent surface, comprising implanting Ti or N into the surface of the stent on a molecular or atomic level, followed by implanting TiN over the Ti or N, and followed by forming a layer of a TiN_xO_y compound over at least some of the areas where TiN has been implanted.
20. (Canceled)
21. (Currently Amended) A stent comprising: a first region having Ti or N implanted on a molecular or atomic level at a depth ~~with~~within at least a region of a surface of the stent~~[[,]]~~; a second region over the first region having TiN implanted on a molecular or atomic level at a depth ~~with~~within at least a region of a surface of the stent; and a layer of TiN_xO_y compound over the second region.
22. – 23. (Canceled)
24. (Previously Presented) The stent of Claim 21, wherein the stent is made from stainless steel.
25. (Previously Presented) The stent of Claim 21, wherein the surface is the tissue-contacting surface of the stent.
26. (Withdrawn) A stent comprising a layer of TiN_xC_y exposed on the surface of the stent, the stent having a surface material different than TiN_xC_y and a compound including Ti, N, or TiN, disposed beneath the layer of TiN_xC_y such that the compound is blended with the surface material of the stent.
27. (Withdrawn) The stent of Claim 26, wherein a region of the layer of TiN_xC_y is implanted at a depth within a surface of the stent.

28. – 33. (Canceled)

34. (Withdrawn) A stent comprising a TiN_xC_y compound implanted on a molecular or atomic level at a depth within at least a region of a surface of the stent.

35. – 41. (Canceled)

42. (Withdrawn) The stent of Claim 34, additionally comprising a layer of a TiN_xC_y compound on the region of the surface of the stent wherein the TiN_xC_y compound is implanted.

43. (Withdrawn) A method of modifying a stent surface, comprising implanting on a molecular or atomic level Ti, N, or TiN into the surface of the stent and forming a layer of a TiN_xC_y compound over the areas where Ti, N, or TiN has been implanted.

44. (Withdrawn) A method of modifying a surface of a stent, comprising implanting a TiN_xC_y compound on a molecular or atomic level at a depth within a surface of the stent or depositing the compound on the surface of the stent.

45. (Withdrawn) The stent of Claim 1, wherein the layer of TiN_xC_y is exposed on a surface of the stent.

REMARKS/ARGUMENTS

The status of the claims with respect to the status of claims at the time of the non-final Office Action of July 9, 2008 is described. Claims 1 – 10, 13, 14, 17 – 19, 21, 24 – 27, 34, and 42 – 45 are pending. Claims 1, 7 – 10, 13, 14, 17, 18, 26, 27, 34, and 42 – 45 have been withdrawn. Withdrawn claims 1, 13, and 18 are amended. Claim 21 is amended.

Reconsideration is respectfully requested in view of the remarks below.

Claim Rejections - 35 USC § 103

Claims 2 – 6, 19, 21, 24, and 25 are rejected under 35 U.S.C. §103(a) as being unpatentable over Lazarov et al., United States Patent No. 6,110,204 (“Lazarov”), in view of Malik et al., *J. Vac. Sci. Technol. A*, 15(6), Nov/Dec 1997 (“Malik”).

Applicants respectfully traverse the Examiner’s rejection. First, the Examiner has made an error in interpreting Malik’s disclosure. The Examiner is incorrect, Malik does not “teach implantation of various metallic compounds (including Ti, N, and O). . . .” By stating “[a]fter sputter cleaning, the substrate may be implanted with a relevant ion species for improved adhesion” (page 2876, column 1, lines 10 – 12) Malik teaches the general concept of ion implantation. The only specific example of implantation provided was the implantation of carbon ions (page 2877, column 1, lines 9 – 11). Therefore, with the exception of carbon ions, there is no teaching of what the term “relevant ions” means. Malik does not teach the implantation of Ti or its alloys, but teaches use of a Ti as a sputtering target.

Second, regardless of the Examiner’s misinterpretation of Malik, the combination fails to teach what has been claimed. Lazarov and Malik, alone or in combination, fail to teach the tri-region construct as claimed in claims 19 and 21. More specifically, the references fail to teach “first region having Ti or N implanted on a molecular or atomic level at a depth within at least a

region of a surface of the stent; a second region over the first region having TiN implanted on a molecular or atomic level at a depth within at least a region of a surface of the stent; and a layer of TiN_xO_y compound over the second region,” as recited by claim 21 and “implanting Ti or N into the surface of the stent on a molecular or atomic level, followed by implanting TiN over the Ti or N, and followed by forming a layer of a TiN_xO_y compound over at least some of the areas where TiN has been implanted,” as recited by claim 19. The Examiner admitted “Lazarov reference does not disclose the compound [titanium-nitride-oxide (TiN_xO_y)] is implanted on a molecular level within the surface of the stent.” As noted above, Malik only teaches the implantation of carbon ions and other unspecified “relevant ions.” The Examiner has not explained how the combination of the two references would have led one of ordinary skill in the art to the device of claim 21 with the two regions and a layer on top of the second region, or the method of claim 19 which involves the three processing steps. Therefore, claims 19 and 21, as well as claims dependent thereon, are allowable over Lazarov in view of Malik.

Applicants respectfully request the removal of the rejection under 35 U.S.C. §103(a) of claims 2 – 6, 19, 21, 24 and 25, and allowance of these claims.

Conclusion

In light of the foregoing claim amendments and remarks, this application is considered to be in condition for allowance. Applicants respectfully request the allowance of claims 2 – 6, 19, 21, 24, and 25. Applicants reserve the right to file a divisional application for restricted but unelected Species II from the restriction requirement of June 6, 2004.

If necessary to ensure a timely response, this paper should be considered as a petition for an Extension of Time sufficient to provide a timely response. The undersigned authorizes the

Commissioner to charge any fees that may be required, or credit of any overpayment to be made,
to the **Squire, Sanders, and Dempsey Deposit Account No. 07-1850.**

Should the Examiner have any questions regarding this communication, the Examiner is
invited to contact the undersigned at the telephone number shown below.

Respectfully submitted,

Dated: February 24 2009
Squire, Sanders & Dempsey L.L.P.
One Maritime Plaza, Suite 300
San Francisco, CA 94111
Telephone (415) 954-0397
Facsimile (415) 393-9887

By Gloria M. Gusler
Gloria M. Gusler
Attorney for Applicants
Reg. No. 50,282

Electronic Acknowledgement Receipt

EFS ID:	4846984
Application Number:	09997450
International Application Number:	
Confirmation Number:	3442
Title of Invention:	Modified surface for an implantable device and a method of producing the same
First Named Inventor/Applicant Name:	Shamim M. Malik
Customer Number:	45159
Filer:	Gloria M. Gusler/Tomika Thomas
Filer Authorized By:	Gloria M. Gusler
Attorney Docket Number:	50623.061
Receipt Date:	24-FEB-2009
Filing Date:	30-NOV-2001
Time Stamp:	15:58:57
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		050623_00061_Response_to_N otice_dated_27Jan09.pdf	271759 21ba295dc48ac343a51cbec6b8f066e1348 bd59c	yes	8

	Multipart Description/PDF files in .zip description		
	Document Description	Start	End
	Supplemental Response or Supplemental Amendment	1	1
	Claims	2	5
	Applicant Arguments/Remarks Made in an Amendment	6	8

Warnings:

Information:

Total Files Size (in bytes):	271759
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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

X. Related Proceedings Appendix

There are no related proceedings.